UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

Civil Action: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO ALL ACTIONS

Judge Patti B. Saris

DEFENDANT AMGEN INC.'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION FOR A CONTINUED LIMITED STAY OF DISCOVERY

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I. Introduction

Following the November 21, 2003 hearing, Amgen Inc. filed a straightforward motion seeking the simple and limited relief that discovery against it be stayed until the Court rules on Amgen's individual motion to dismiss. Plaintiffs have responded with a rambling opposition that is remarkable in two basic respects: (1) it does not dispute that Amgen would be significantly prejudiced and Plaintiffs would not be prejudiced if a stay is not entered; and, (2) despite its length, it fails to address in any meaningful way Plaintiffs' failure to provide specific allegations to support the fraud claims against *Amgen*, instead it focuses on generalities, devotes its bulk to a discussion of a ruling by *another* judge on *another* complaint against *another* defendant that is indisputably different from Amgen and discusses non-AWP based (and hence irrelevant) reimbursement issues.

II. Argument

A. Plaintiffs do not dispute that Amgen will be substantially burdened absent a stay.

Plaintiffs do not address, let alone dispute, that Amgen will be prejudiced if a stay is not entered. This is not surprising since, as Amgen predicted in its motion, Plaintiffs have now propounded broad requests to Amgen calling, for example, for the production of all documents relating to pricing, rebates, grants, customer invoices, and sales and marketing practices for each of six drugs (virtually all of Amgen's products) over a 13 year period. *See* Plaintiffs' Requests for Production of Documents, attached as Exhibit A to Hoffman-La Roche Inc.'s Motion for a Continued Stay of Discovery, at Request Nos. 6, 7, 10, 14, 26-27, 30.[1] Plaintiffs can hardly take the position that such discovery is not unduly burdensome in light of their own recently-filed Motion for a Protective Order Regarding Subpoenas to Putative Class Members, in which they

[1] Despite being specifically advised that three of the named products – Epogen, Kineret and Enbrel – are either not reimbursed under Medicare Part B or are not reimbursed based upon AWP, Plaintiffs unreasonably continue to demand wide-ranging discovery as to these products.

argue that *significantly more narrow* requests to so-called absent class members is unduly burdensome. *See* Memorandum in Support of Plaintiffs' Motion for a Protective Order Regarding Subpoenas to Putative Class Member, a copy of which is attached hereto as Exhibit 1, at 11-12. Indeed, the Court itself has recognized the inherent prejudice to a defendant in Amgen's position. *See* 1/13/03 Hearing Tr. at 117 attached as Exhibit 2 to Amgen's motion) ("I don't want people spending a fortune on something which may be a much pared-down case, if any. … I don't want people to be battering back and forth on discovery at this point [during the pendency of the motions to dismiss].").

B. Plaintiffs do not dispute that a limited stay will not prejudice them, nor be disruptive to the case more generally.

Likewise, Plaintiffs do not dispute that they will not be prejudiced by Amgen's request for a brief continued stay of discovery, again choosing simply not to take the issue on in their opposition papers. The relief sought by Amgen is narrow: Amgen seeks only a brief additional stay of discovery as to it, until the Court has assessed the merits of its individual motion to dismiss. Moreover, the granting of Amgen's motion will not unduly complicate or delay these proceedings. Indicative of the genuinely different position in which Amgen finds itself (given the paucity of the allegations against it), Amgen's motion has not lead to a cavalcade of copycat filings. To date, only one other defendant – Hoffman-La Roche – which faces equally deficient allegations, has filed a similar motion.

C. Amgen's Motion to Dismiss is a "likely winner."[2]

It is telling that Plaintiffs persist in ignoring the AMCC's meager allegations against Amgen and instead point to anything else in an effort to draw attention away from those allegations. Plaintiffs, for instance, devote nearly half of their opposition to a discussion of Judge Stearns' recent assessment of the claims against TAP Pharmaceuticals in the *Lupron* litigation rather than defend their own allegations against Amgen, allegations that are at the very core of the motion to which they are supposedly responding.

Rule 9(b)'s dictate is crystal clear. It requires Plaintiffs to allege the circumstances of Amgen's supposed fraud with particularity. Clearly, Plaintiffs' allegations against Amgen do not meet this basic mandate. Plaintiffs' AMCC merely recites generalities that Amgen: "engages in an organization-wide scheme to inflate AWPs;" "has stated fraudulent AWPs for all or almost all of its drugs;" "has controlled and set the AWPs for its pharmaceutical products;" and "has utilized hidden inducements." There is not a single particularized allegation of fact underlying any of these assertions that Amgen actually did any of these things. As to Amgen, Plaintiffs' case remains nothing more than an unfounded and unsupported hypothesis.

Plaintiffs have repeatedly extolled to the Court their claims of exhaustive investigations and careful assessments leading to the AMCC's allegations and their decision to include or to exclude particular manufacturers and particular drugs. Despite these efforts, the AMCC is devoid of anything to support the blanket assertion that Amgen committed fraud: there is no description of any Amgen practice of marketing the "spread;" the AMCC provides no example of any communication between Amgen and the compendia or any third party about the

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[2] Amgen does not respond to Plaintiffs' somewhat curious discussion of its RICO enterprise allegations (Opposition at 9-11) given that Amgen's defendant-specific arguments for dismissal were grounded entirely on Rule 9(b). Apparently, this discussion by Plaintiffs is nothing more than a gratuitous attempt to supplement their consolidated memorandum on the RICO enterprise issue following the oral argument on the motions to dismiss the AMCC.

"spread;" it does not cite to even a single internal document implying that Amgen engaged in any improper pricing, marketing or reimbursement practices; and it is undisputed that, unlike virtually any other defendant in the AMCC, Amgen has not been the subject of a single Congressional, OIG, DOJ or other investigation or inquiry into AWP. [3]

Plaintiffs must do more than merely allege generalities as to "defendants" (or even, as they claim, specifics as to certain defendants) and then, when it comes time to detail Amgen's supposed fraud, assert that it is a "logical inference" that Amgen engaged in such conduct too. *Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 877-78 (1st Cir. 1991). Yet, in a truly remarkable admission, this is all Plaintiffs have done. *See* AMCC at ¶ 221 ("Amgen also know that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, *the competing manufacturers' manipulate the AWP* to create a reimbursement advantage for their drugs.... All of *these competing drugs are alleged herein to be subject to AWP manipulation. The logical inference is that Amgen also engaged in AWP manipulation* for those drugs where the competitors were manipulating and marketing the AWP spread.") (emphasis added).

Plaintiffs' dire prediction that compliance with Rule 9(b) will result in complaints requiring several thousands of pages is pure smokescreen. As to several defendants, the Court has already determined the allegations sufficient under Rule 9(b), and those claims have not required inordinate length. Even if this were not the case, it should not be surprising that a complaint alleging fraud against dozens of companies for hundreds of drugs may require a lengthy pleading. The MDL process is not intended to deny each defendant the modicum of individual procedural due process reflected in and required by Rule 9(b).

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[3] For the Court's convenience, the Amgen-specific allegations of the AMCC are set forth in their entirety in the attached Exhibit 2.

Plaintiffs' reliance on Judge Stearns' decision in the *Lupron* litigation and their assertion that the complaint in that case is "nearly identical" to the AMCC is absurd. While both cases may involve allegations of AWP manipulation, that is where the similarities end. Unlike the AMCC, the TAP complaint, a copy of which is attached as Exhibit 3, is largely directed to a single pharmaceutical manufacturer, TAP. The TAP complaint contains over 200 paragraphs of specific factual allegations against TAP as opposed to the AMCC's generalities about most of the pharmaceutical industry, and Amgen in particular. These factual allegations of TAP's supposed fraudulent conduct served as the basis for Judge Stearns' decision.

Unlike the AMCC's allegations against Amgen, the TAP complaint includes particularized allegations concerning specific alleged TAP marketing plans ("Return to Practice") (Exh. 3 at ¶ 69, 73), specific alleged spreads between AWP and average sales price as to TAP's Lupron® (Exh. 3 at ¶ 70), the alleged provision of free samples to practitioners to reduce actual sales price (and to increase spread) (Exh. 3 at ¶ 82, 85, 92), the alleged use of unrestricted educational grants to induce purchases and further reduce actual prices paid (Exh. 3 at ¶ 101, 105), alleged communications by upper-level management reflecting the company's efforts to conceal actual pricing information (Exh. 3 at ¶ 112), and the alleged use of other vehicles, including debt forgiveness, as a hidden discounts (Exh. 3 at ¶ 117).

Not one of these detailed allegations is present in Plaintiffs' allegations against Amgen. The TAP complaint also draws upon charging documents and TAP's guilty plea to criminal charges and its agreement to pay $875 million in civil and criminal fines and penalties. In stark contrast, Plaintiffs cannot muster anything approaching this level of detail against Amgen, unable even to allege that Amgen has been a subject of, let alone plead guilty in connection with, any government inquiry or investigation regarding improper manipulation of

AWP, the "spread," or other supposedly improper marketing inducements. Plaintiffs' effort to compare Amgen with TAP is not only unsupported, but is unseemly and serves only to underscore the absence of the requisite details as to Amgen. Judge Stearns merely applied well-established Rule 9(b) precepts to a radically different and appreciably more detailed set of factual allegations and declared that *those* allegations were adequate to allow portions of the complaint in that case to stand. His decision does not mean that the allegations *here* suffice.

Lastly, Plaintiffs again refer to a decade-old OIG report and to the published opinion in *Amgen Inc. v. Scully*, 234 F.Supp. 2d 9 (D.D.C. 2002). Both of these arguments are absolute red herrings. As Amgen has repeatedly noted in response to similar references in virtually every memorandum filed by Plaintiffs in these cases (to which Plaintiffs have yet to respond in any substantive fashion), the OIG report was prepared in connection with the U.S. Department of Health and Human Services' consideration more than 10 years ago of possible changes to the ***statutorily fixed reimbursement rate (i.e., not AWP-based reimbursement)*** for Epogen. How that report (or Amgen's unwillingness to provide sensitive pricing information to HHS without appropriate safeguards governing its dissemination) serves to support Plaintiffs' conclusion that Amgen must have been involved in AWP manipulation remains a great mystery that Plaintiffs have yet to resolve. Indeed, as Amgen has suggested elsewhere, it is more reasonable to infer the absence of any improper manipulation than it is to infer misconduct, as plaintiffs ask this Court to do, given the government's obvious awareness of Amgen's rebate and pricing for Epogen, and the lack of any investigative interest or follow-up.[4]

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[4] The study, moreover, did not suggest that Amgen's rebates were in any way improper. In fact, although OIG recommended that HCFA consider reducing the statutory reimbursement rate to reflect end-of-year rebates, HCFA rejected that recommendation, noting "that the elimination of rebates . . . would not result in a change in the manufacturer's price, nor would it serve any program end." OIG A-01-92-00506 (incorrectly cited by plaintiffs as OIG A-01-02-00506).

Similarly, Plaintiffs reference to *Scully* as supporting an inference that Amgen engaged in "over-reimbursement marketing strategies" is misguided. In that case, Amgen merely challenged under the APA a decision by HHS to reduce Medicare reimbursement for Amgen's product, Aranesp®. The district court held that Amgen did not have standing to challenge the agency's action under the APA because it was not an intended beneficiary under Medicare. The case (which is outside of the pleadings in any event) simply cannot be read to support the proposition that Amgen engaged in, much less acknowledged its involvement in, the unlawful manipulation of AWP.

At bottom, Amgen exhorts the Court to take a step back, carefully examine the supposedly "specific" allegations against Amgen in the AMCC (attached as Exhibit 2) and determine for itself whether those allegations are adequate to expose a defendant, like Amgen (and any other defendant where the Court has not yet had the opportunity to do so), to protracted and costly litigation, in light of this Court's prior rulings and First Circuit precedent. *See, e.g., U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp.2d 39, 46 (D. Mass. 2001); *Romani,* 929 F.2d at 877-78. *See also In re Pharmaceutical Indus. Avg. Wholesale Price Litig.,* 263 F.Supp.2d 172, 194 (D. Mass. 2003).

III. Conclusion

For the reasons set forth herein, and in Amgen's initial submission, Amgen requests that its motion be granted and that the Court continue the previously imposed stay of discovery, as to Amgen, pending the Court's consideration and ruling on Amgen's individual motion to dismiss the AMCC.

Respectfully submitted,

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Dated: December 9, 2003

CERTIFICATE OF SERVICE
I hereby certify that a true copy of the above document was served upon the attorney of record for each other party ~~by mail-hand~~ electronically on 12-10-03
Frank A. Libby